

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k031727

B. Analyte:

Gemifloxacin at 0.015-4 ug/ml

C. Type of Test:

Quantitative – broth based growth detected by turbidity

D. Applicant:

Pasco Laboratories – BD Diagnostics System

E. Proprietary and Established Names:

Pasco MIC and MIC/ID Panels

F. Regulatory Information:

1. Regulation section:
866.1640 - Antimicrobial Susceptibility Test Powder
2. Classification:
II
3. Product Code:
JWY - Manual Antimicrobial Test Systems
4. Panel:
83 - Microbiology

G. Intended Use:

1. Intended use(s):
Pasco MIC and MIC/ID panels are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement or category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of these organisms.
2. Indication(s) for use:
The inclusion of the antibiotic gemifloxacin (0.015-4 ug/ml) on the gram negative panels for testing of Enterobacteriaceae and Acinetobacter spp.
3. Special condition for use statement(s):
4. Special instrument Requirements:

H. Device Description:

Various concentrations of antimicrobial agents (usually in two-fold dilutions) are dispensed into the Pasco microdilution panels and the panels are then frozen. Panels are thawed prior to use, inoculated with the test organisms, incubated the traditional 16-24 hours at 35° in a non-CO₂ incubator and panels are then observed for visible growth or color changes (ID portion). The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory

concentration (MIC). Only manual readings are performed using an indirect lighted background viewer.

Inoculation procedures include the Direct Turbidity Standard method and Stationary Phase methods which use a spectrophotometer to equate the suspension to a 0.5 McFarland and the Director™ Inoculation System which does not use a spectrophotometer.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Pasco MIC Panels
2. Predicate K number(s):
K030933 moxifloxacin
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Type panel	100 µl/well frozen	100 µl/ml frozen
Inoculum	5 µl	5 µl
Inoculation method	Direct equated to a 0.5 McFarland or Director™ Inoculation System	Direct equated to a 0.5 McFarland or Director™ Inoculation System
Incubation	16-24 hours	16-24 hours
Reading method	Visual growth	Visual growth
Final inoculum/well	2-5 x 10 ⁵	2-5 x 10 ⁵
Differences		
Item	Device	Predicate
Antibiotic tested	gemifloxacin	moxifloxacin

J. Standard/Guidance Document Referenced (if applicable):

“Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA”; NCCLS Standard M7 *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically*; Approved Standard; M100 *Performance Standards for Antimicrobial Susceptibility Testing*

K. Test Principle:

The test panels are dependent on the growth of the organisms in the presence of the antibiotics. The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC).

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Ten isolates with on-scale results were tested at three sites. These were evaluated for site to site reproducibility and inter site reproducibility using the ten isolate

study described in the guidance document (10 organisms tested 3 times on 3 days at 3 sites). The testing of the challenge set of organisms was used to augment this study. These were tested at only 2 sites but there were 51 additional gram negative isolates with on scale results with very good performance.

This study was performed on both the turbidity standard method and the Director™ Inoculation System method. Both were >95% reproducible intra site and inter site. Within site can also be observed using the test results performed on the QC isolates at each site. All sites had acceptable within site reproducibility.

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

The recommended QC isolates were tested a sufficient number of times with acceptable results with the reference method. The Pasco results demonstrate that the system can produce QC results in the recommended range for both the Direct turbidity and the Director™ Inoculation System methods of inoculation. The two different inoculation methods had the same mode.

ORGANISM	conc	Reference	Pasco turbidity	Pasco Director™
E. coli ATCC 25922	≤ 0.015	138	138	110
Range ≤ 0.015				
P aeruginosa ATCC 27853	0.12			
Range 0.25-1 (NCCLS)	0.25	42	48	1
	0.5	96	90	105
	1			4
	2			

Inoculum Density Check- An internal study was performed to verify the colony counts (CC) that would be obtained with each method of inoculation. CC demonstrated that the Pasco turbidity inoculation results in a slightly less concentration of organisms than the reference method. The Director™ Inoculation System method appeared to have a wider range of results. Clinical site inoculum density checks were also performed on QC isolates with the Director™ Inoculation System method and the Turbidity method. The Director™ Inoculation System produces a slightly higher inoculum than the Pasco turbidity method, which is consistent with the internal colony count studies.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:a. *Method comparison with predicate device:*

Broth reference panels prepared according to the recommendations of the NCCLS were used to compare to the Pasco results. Testing was performed at 3 sites and included fresh (78%) and stock (22%) clinical isolates and a set of challenge organisms. The comparison resulted in the following performance evaluations for the gram negative panel.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Clinical	517	516	99.8	225	224	99.6	513	99.2	142	4	0	0
Challenge	98	97	99	47	47	100	97	99	18	1	0	0
Combined	615	613	99.7	272	271	99.6	610	99.2	160	5	0	0

EA-Essential Agreement

CA-Category Agreement

R-resistant isolates

maj-major discrepancies

vmj-very major discrepancies

min- minor discrepancies

EA is when there is agreement between the reference method and the Pasco panel within plus or minus one serial two-fold dilution of antibiotic. CA is when the interpretation of the reference method agrees exactly with the interpretation of the Pasco result. The %EA and CA are acceptable with acceptable discrepancy rates when compared to the reference method as described in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA".

Testing of the challenge set was also performed using the Director™ Inoculation System method of inoculation demonstrating little difference between the two methods of inoculation. Summary table of the Director™ Inoculation System follows:

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Challenge	98	98	100	50	50	100	97	99	18	1	0	0

b. *Matrix comparison:*

Not applicable

3. Clinical studies:a. *Clinical sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

c. *Other clinical supportive data (when a and b are not applicable):*4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

≤ 0.25 (S); 0.5 (I); ≥ 1 (R)

The interpretative criteria are the same as the FDA approved criteria and will appear on the worksheets and will be noted only for Enterobacteriaceae and Acinetobacter spp..

M. Conclusion:

Data analysis when performed as recommended in the “Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA” demonstrates that the Pasco System is substantially equivalent to the predicate.